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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/606,314

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EXAMINER

SCHUBERG, LAURA J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

10/21/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/606,314	Applicant(s) FIKE ET AL.	
	Examiner LAURA SCHUBERG	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 27,36,93-95,103,110,111,122-124,126-137 is/are pending in the application.
- 5a) Of the above claim(s) 27,36,93-95,103,110,111 and 122 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 123,124,126-137 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This action is responsive to papers filed 08/08/2011.

Claims 27, 36, 93-95, 103, 110, 111, 122-124, 126-137 are currently pending.

No claims have been amended, newly canceled or newly added.

Claims 27, 36, 93-95, 103, 110-111 and 122 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/10/2010. The restriction requirement has been made Final.

Claims 123, 124 and 126-137 have been examined on their merits.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 123, 124, 126-134 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfe (EP 0283942) in view of Fassolitis et al (Applied and Environmental Microbiology 1981), Peebles (US 2,835,586) , Prestrelski et al (US 5,580,856) and Franklin (US 5,869,321).

Applicant claims an agglomerated mammalian cell culture medium powder prepared by agglomerating a dry powder mammalian cell culture medium with a solvent;

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wherein said agglomerated powder exhibits reduced dusting and a larger particle size than does the non-agglomerated medium powder.

Wolfe teaches a chemically defined basal nutrient medium used for serum-free culture or supplemented with low levels of serum for high and low density culture. The cell culture medium powder taught by Wolfe also comprises a biological buffer, *e.g.*, alpha-glycerolphosphate or N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid (HEPES) (page 2, lines 46-49). Genetically engineered proteins (recombinant proteins) are suggested as suitable for inclusion in a media composition (page 2 lines 39-40). A preferred protein supplement is insulin for murine hybridomas (page 6 lines 5-9). A pH of about 7.0 to about 7.4 is suggested with a pH of about 7.35 being preferred (page 5 lines 12-16).

Wolfe does not specifically teach wherein the powder cell culture media is agglomerated.

Fassolitis et al teach a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial cells or "animal cells" (mammal) using a powdered nonfat dry skim milk filtrate (NDMF) as an animal cell culture medium (page 201, Column 1, under "Preparation of milk fraction"), wherein Fassolitis et al teach a method of making NDMF comprising reconstituting a dry milk powder. On page 200, Column 2, under "Cell culture medium", Fassolitis et al teach a cell culture medium supplemented with 5% NDMF and HEPES, wherein the pH of the medium was adjusted to 6.8 to 7.4 that is used to propagate epithelial cells (*see* Table 1 on page 201).

Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture (column 2 lines 13-70). The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting (claims and Column 9, lines 46-54). With regard to the claim limitation “wherein said agglomerated powder upon being reconstituted with water supports the proliferation or cultivation of a mammalian cell *in vitro*” of Claim 27, as evidenced by the teachings Fassolitis the prior art agglomerated dry powder taught by Peebles is considered as an agglomerated mammalian cell culture medium powder that is able to support the proliferation or cultivation of a mammalian cell *in vitro* upon reconstituted with water and inherently having the claim-designated pH range.

Prestrelski et al teach a spray-drying method that is applied to protein compositions in order to stabilize them for long term storage (column 1). Suitable proteins include those used in cell culture media compositions such as growth factors and insulin (column 6 lines 40-54).

Franklin teaches an agglomerated culture medium that includes proteins, carbohydrates, and salts for the culture of microorganisms (columns 9-10).

It would have been obvious for one of ordinary skill in the art to include the agglomerated spray-dried milk powder of Peebles in the media composition of Wolfe as a serum substitute. One of ordinary skill in the art would have been motivated to do so

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because Wolfe teaches that a serum-free composition is desirable. One of ordinary skill in the art would have had a reasonable expectation of success because Fassolitis teaches that dried milk powder is a suitable substitute for serum in the culture of animal cells and Franklin teaches that agglomerating culture media for microorganisms has been successful, includes many of the same nutrients as animal medium and provides numerous advantages over non-agglomerated media (column 2 line 63- column 3 line 10). One of ordinary skill in the art would have been motivated to formulate the entire cell culture media as an agglomerated dry powder because Peebles teaches that it does not require vigorous or prolonged agitation to make a desired stable dispersion and it is easy to remove from a container and poured from a spout without plugging or dusting (column 9 lines 45-57). One of ordinary skill in the art would have had a reasonable expectation of success because Prestrelski et al teach that it is desirable to spray-dry a protein composition containing insulin and growth factors (which are present in the Wolfe composition) in order to stabilize them for long term storage.

Therefore the combined teachings of Wolfe, Peebles, Fassolitis et al and Prestrelski et al and Franklin render obvious Applicant's invention as claimed.

Claims 135-137 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfe (EP 0283942) in view of Fassolitis et al (Applied and Environmental Microbiology 1981), Peebles (US 2,835,586), Prestrelski et al (US

5,580,856) and Franklin (US 5,869,321) as applied to claims 123, 124, 126-134 above, and further in view of Wyatt et al (WO 94/28944).

Claims 135-137 include wherein the agglomerated powder is sterilized by irradiation and after packaging.

The combined teachings of Wolfe, Peebles, Fassolitis et al and Prestrelski et al render obvious Applicant's invention as described above, but are silent with regard to the sterilizing of the media compositions.

Wyatt et al teach a method wherein powder medium is stored in a bag and then subjected to gamma irradiation for sterilization. Wyatt et al teaches that since this invention eliminates the need for post-mixing sterilization, it reduces the potential for loss of product or components, thereby increasing batch-batch consistency (page 2 lines 9-15).

Therefore one of ordinary skill in the art would have been motivated to sterilize the packaged powdered media of Wolfe by gamma irradiation because Wyatt et al teach that this reduces the potential for loss of product or components, thereby increasing batch-batch consistency (page 2 lines 9-15). One of ordinary skill in the art would have had a reasonable expectation of success because Wyatt et al and Wolfe are both drawn to powder medium compositions.

Therefore the combined teachings of Wolfe, Peebles, Fassolitis et al and Prestrelski et al and Wyatt et al render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 08/08/2011 have been fully considered but they are not persuasive.

Applicant argues that the cited prior art alone or in combination do not render obvious Applicants' inventive agglomerated dry, mammalian cell culture medium powder as presently claimed.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The prior art references demonstrate that the agglomeration of culture media is known in the prior art as described by Franklin and that there are well known advantages achieved when dried powders are agglomerated as well as described by Peebles. Mammalian cell culture media that are preferred in dried powder form are also known in the prior art as well as described by Wolfe and Fassolitis.

Applicant argues that the final medium in Fassolitis is not dry, but is a liquid and therefore Fassolitis is not drawn to a dry powder cell culture medium.

This is not found persuasive because cell culture media are only kept in powdered form for storage purposes. When a powder media is to be used for cell

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culture it must be reconstituted with a liquid so that a final media is eventually always in a liquid form for use.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Schuberg/
Primary Examiner
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